1. 35 U.S.C. §112 Rejections

Claims 1-8 have been rejected under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention.

The Office states that "In claim 1, line 1, it is not clear what is meant by the IOL system 'comprising and insertion and injection device and a deflated lens member.' Comprising what and insertion and injection device and a deflated lens member? In line 6 it is not clear what is meant by the deflated lens member is mounted 'about and to an end of the moveable member'. About what and to an end of the moveable member?"

Applicants have amended claim 1 to correct typographical errors and for clarification. Claim 1 now reads "An intraocular lens system comprising an insertion and injection device." Regarding the term "wherein the deflated lens member is mounted about and to an end of the moveable member such that the deflated lens member is sealingly engaged with a portion of the moveable member so that the interior of the deflated lens member forms a compartment", Applicants respectfully submit that this terminology is sufficiently clear and that no amendment is required.

Applicants respectfully submit that the essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) The content of the particular application disclosure; (B) The teachings of the prior art; and (C) The claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. (See MPEP 2173.02)

The claim terminology "the deflated lens member is mounted about and to an end of the moveable member" means just that – the deflated lens member is mounted about an end of the movable member and is mounted to an end of the movable member. This is shown clearly in Fig. 3, wherein the lens (146) is shown about (i.e.

surrounding) a portion of the moveable member (130). The lens is mounted such that the lens member "is sealingly engaged with a portion of the moveable member so that the interior of the deflated lens member forms a compartment" (see claim 1). In other words, the lens member surrounds a portion of the moveable member.

The Office further states "In claim 2, line 2, 'moveable disposed' would appear to be --moveably disposed--."

Claim 2 has been amended as suggested to correct the typographical error.

The Office further states "In claim 7, line 2, it is not clear what is meant by the self-sealing mechanism 'in which is removably and sealingly received the moveable member'."

Claim 7 has been amended for clarity to state "the self-sealing mechanism which is removably and sealingly received by the moveable member."

It is respectfully submitted than claims 1-8 comply with 35 U.S.C. §112. Reconsideration and withdrawal of the rejection is respectfully requested.

2. 35 U.S.C. §102 Rejections

Claim 9 has been rejected under 35 U.S.C. §102(b) as being anticipated by Galib. The Office states:

> Galib teaches an insertion and injection device for inserting a deflated lens member comprising a moveable member 65 having an outlet port at the distal end thereof. The deflated lens member is mounted about the end of the moveable member and sealingly engaged with another portion of the moveable member. The moveable member outlet communicates with the deflated member compartment.

Applicants respectfully traverse this rejection.

Applicants claim in claim 9 an intraocular lens system comprising an insertion and injection device and a deflated lens member having an interior. The insertion and

injection device has an outlet member, and the deflated lens member is mounted to the outlet member. Further, the deflated lens member includes a self-sealing mechanism in which the insertion and injection device is removably and sealingly received such that the insertion and injection device can be removably and sealingly received in the self-sealing mechanism repeatedly.

As set out by Applicants, prior intraocular lenses and methods of insertion result in complex lens folding issues and haptic breakage. Further, Applicants set out that:

> A major concern of ophthalmic surgeons is choosing the correct refractive power for lenses. Patients risk additional surgery for lens removal and replacement if the choice of lens refractive power is too much in error. A risk commonly shared in the use of solid, silicon, and gel-type lenses is additional surgery since it is the only alternative for changing a refractive power too much in error. This concern about additional surgery and selecting refractive power becomes of particular concern when dealing with young patients because a rigid lens of the correct refractive power when implanted may not later correctly focus light entering the eye and passing to the retina due to the changing in the size and shape of the eyeball in very young patients as they mature.

Page 3, lines 16-26.

Thus, Applicants teach an intraocular lens system that minimizes haptic breakage and concerns with lens manipulation within the lens capsule. Applicants further provide an intraocular lens system wherein the refractive power of the lens can be selectively adjusted by regulating the material being injected. Applicants further teach a lens whereby the refractive power can be adjusted following implantation at a later time during the life of the patient to compensate for changing conditions of the eye. Applicants accomplish this by providing a lens that has a self-sealing mechanism in which the insertion and injection device is removably and sealingly received. The insertion and injection device can be sealingly received in and removed from the self-sealing mechanism repeatedly. To insert the lens member into the eye, a portion of the insertion and injection device is inserted into the eye with the deflated lens member. The insertion and injection device then injects a medium into the interior of the deflated lens member, thereby inflating the lens member. The refractive power of the lens can be adjusted by the amount and/or type of medium injected. The self-

sealing mechanism forms a seal about the insertion and injection device to prevent leakage of medium as it is injected into the lens. After the lens member is inflated, the insertion and injection device is removed from the self-sealing mechanism of the lens and a seal is automatically formed to prevent medium within the lens from leaking. In the event that the refractive power of the lens must be changed at a later time, an incision is simply made into the eye to provide access to the lens. An injection device is then inserted into the self-sealing mechanism, which forms a seal about the injection device, and medium is injected or removed as required. Thus, contrary to prior methods and devices, in the event that the required refractive power of an intraocular lens changes, the intraocular lens does not have to be removed and a new intraocular lens does not have to be inserted in its place. Rather, the refractive power of the intraocular lens within the eye can simply be adjusted.

The Galib reference, on the other hand, describes an intraocular lens having a hollow body portion 42 and a hollow neck portion 44. According to Galib, the intraocular lens is inserted into the eye by inserting a hollow rod or stylet 65 into the hollow neck portion and body portion and pushing the stylet with the intraocular lens mounted thereon into the eye. The body portion is then distended by inserting a material. After then body portion is distended, as set out by Galib,

> * * * its neck portion 44 is closed off immediately adjacent the body portion 42 of the bag either by a suitable suture or surgical knot or by a suitable thermal sealing process. The region of the neck portion beyond the resulting seal and extending through the incision 30 is detached and removed through the incision 30. When the iris 18 is allowed to return to its normal position, it covers the site of the seal, and the seal is sufficiently remote from the central region of the lens that it does not substantially interfere with the normal passage of light therethrough.

Col. 6, lines 18-29.

As provided in MPEP-2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Or stated another way, "The identical invention must be shown in as complete detail as is contained in the ... claims. *Richardson v Suziki Motor Co.*, 868 F.2d 1226, 9 USPQ 2d. 1913, 1920 (Fed. Cir. 1989). Although identify

of terminology is not required, the elements must be arranged as required by the claim. *In re Bond*, 15 USPQ2d 1566 (Fed. Cir. 1990).

Applicants respectfully submit that each and every element as set forth in the claim is not found, either expressly or inherently, in the cited reference. In particular, the Galib reference does not describe or otherwise suggest Applicants' intraocular lens system having a self-sealing mechanism in which the insertion and injection device is removably and sealingly received such that the insertion and injection device can be removably and sealingly received in the self-sealing mechanism repeatedly. Rather, the lens described by the Galib reference, once inserted and filled with material, is manually closed off either by sutures, a surgical knot or by a thermal sealing process. Thus, once the lens described by Galib is inserted, filled and manually closed off, one cannot later access the interior of the lens to adjust the amount of material within the lens because the lens is permanently sealed.

Thus, it is clear from the foregoing remarks that claim 9 is not anticipated by the Galib reference.

3. 35 U.S.C. §103 Rejections

Claims 1-7 and 10-20 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Galib in view of Sahatjian. The Office states:

> Galib may not teach an outer member for supporting the moveable member however, using a catheter for housing the moveable member to aid in passing the system within the opening in the eye to the deploying site is conventional in the art of inserting inflatable devices within openings in the body. Such would have been an obvious provision and is exemplified by Sahatjian. It would have been obvious to one of ordinary skill in the art to modify Galib to use a catheter for housing and supporting the moveable member and deflated member as taught by Sahatjian in order to aid passing the inflatable member through the opening in the eye. Regarding claim 5, 6, the number of outlets is well within the realm of the artisan of ordinary skill and an obvious provision as desired or required.

Applicants respectfully traverse this rejection.

Applicants claim, in claim 1, an intraocular lens system comprising an insertion and injection device and a deflated lens member having an interior. The insertion and injection device includes a moveable member having an outlet port. The movable member is housed within an outer member. The deflated lens member is mounted about and to an end of the moveable member such that the deflated lens member is sealingly engaged with a portion of the moveable member so that the interior of the deflated lens member forms a compartment. The moveable member outlet communicates with the deflated lens compartment. Further, the deflated lens member includes a self-sealing mechanism in which the insertion and injection device is removably and sealingly received such that the insertion and injection device can be removably and sealingly received in the self-sealing mechanism repeatedly.

The Galib reference, as set out above, describes an intraocular lens having a hollow body portion 42 and a hollow neck portion 44. According to Galib, the intraocular lens is inserted into the eye by inserting a hollow rod or stylet 65 into the hollow neck portion and body portion and pushing the stylet with the intraocular lens mounted thereon into the eye. The body portion is then distended by inserting a material. After the body portion is distended, the neck portion is closed off either by a suitable suture or surgical knot or by a suitable thermal sealing process.

As acknowledged by the Office "Galib may not teach an outer member for supporting the moveable member." The Office, rather, states that "using a catheter for housing the moveable member to aid in passing the system within the opening in the eye to the deploying site is conventional in the art of inserting inflatable devices within openings in the body" and cites Sahatjian.

Applicants respectfully submits that the Galib reference actually teaches away from using such an outer member as required by Applicants' claim 1. Galib states that the use of such outer members are undesirable because, as specifically set forth in Galib:

> Numerous proposals have been made to provide intraocular implants that can be inserted and positioned through the above-described small incision. For example, there are available foldable

> implants that are inserted in a folded condition through the incision and then unfolded while in the eye. These foldable implants are cumbersome to insert and position, oftentimes requiring use of an inserter instrument that can gape the wound or that may necessitate enlargement of the wound to accommodate the inserter instrument along with the implant.

Col. 1 line 60 – col. 2 line 2.

Thus, according to Galib, "to prepare for the insertion operation, a thin blunt-tipped hollow rod, or stylet, 65 is inserted into the bag through its neck portion, and the bag is draped about the stylet as shown in FIG. 4." "The combination of the stylet 56 and collapsed bag draped about it has the cross-sectional form shown enlarged in FIG. 5. The external diameter of this combination is sufficiently small that it can easily be inserted through the small incision 30, which is only 3 or 4 mm in length, without enlarging the incision." (See Col. 5, lines 28-44)

Further, as set out above, according to the Galib reference, after the body portion is distended, the neck portion of the lens is closed off immediately adjacent the body portion either by a suitable suture or surgical knot or by a suitable thermal sealing process. The region of the neck portion beyond the seal and extending through the incision is detached and removed. The Galib reference does not describe or otherwise suggest a lens having self-sealing mechanism in which the insertion and injection device is removably and sealingly received such that the insertion and injection device can be removably and sealingly received in the self-sealing mechanism repeatedly.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must

both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP 2142.

As set out above, the Galib reference does not teach or suggest all of the claim limitations. Specifically, Galib fails to teach or otherwise suggest an intraocular lens system comprising an insertion and injection device and a deflated lens member having an interior wherein the insertion and injection device includes a moveable member having an outlet port and wherein the movable member is housed within an outer member. Further, there is no teaching or suggestion to modify the Galib reference to include such an outer member. Rather, use of an outer member as required by Applicant, is specifically discouraged by the Galib reference as set forth above. Still further, the Galib reference does not describe or otherwise suggest a lens having self-sealing mechanism in which the insertion and injection device is removably and sealingly received such that the insertion and injection device can be removably and sealingly received in the self-sealing mechanism repeatedly. Further, the Sahatjian reference does not remedy these deficiencies in the Galib reference.

Accordingly, claim 1 is patentable over Galib in view of Sahatjian. Claims 2-8 depend from claim 1 and, likewise, are patentable over Galib in view of Sahatjian.

Applicants similarly claim, in independent claim 10, a method for implanting an intraocular lens in an eye. Applicants' method comprises mounting a deflated lens member about and to an end of a moveable member such that the deflated lens member is sealingly engaged with a portion of the moveable member so that an interior of the deflated lens member forms a compartment and such that an outlet port in the moveable member communicates with the deflated member compartment; disposing an outer member about the moveable member; inserting a portion of the outer member within the eye; moving the moveable member from a first position to a second position, thereby deploying the deflated lens member; and forming the intraocular lens by injecting an optical medium into the deflated lens member compartment when the moveable member is in the second position using the moveable member outlet port.

Claim 15 is similar to claim 10 and claims a method for treating one of aphakia or cataract of an affected eye. Applicants' method comprises removing the impaired natural lens of the affected eye; mounting a deflated lens member about and to an end of a moveable member such that the deflated lens member is sealingly engaged with a portion of the moveable member so that an interior of the deflated lens member forms a compartment and such that an outlet port in the moveable member communicates with the deflated member compartment; disposing an outer member about the moveable member; inserting a portion of the outer member within the eye; moving the moveable member from a first position to a second position, thereby deploying the deflated lens member; and forming an intraocular lens by injecting an optical medium into the deflated lens member compartment when the moveable member is in the second position using the moveable member outlet port.

Applicants further claim, in claim 20, a device kit comprising at least one insertion and injection device and a deflated lens member having an interior. Applicants' insertion and injection device includes a moveable member having a outlet port provided therein and an outer member in which is disposed the moveable member. The deflated lens member is mounted about and to an end of the moveable member such that the deflated lens member is sealingly engaged with a portion of the moveable member so that the interior of the deflated lens member forms a compartment. Further, the moveable member outlet communicates with the deflated member compartment.

As set out above, the Galib reference does not describe or otherwise suggest all of Applicants' claim limitations. Specifically, Galib fails to teach or otherwise suggest an intraocular lens system comprising an insertion and injection device and a deflated lens member having an interior wherein the insertion and injection device includes a moveable member having an outlet port and wherein the movable member is housed within an outer member. Further, there is no teaching or suggestion to modify the Galib reference to include such an outer member. Rather, use of an outer member as

required by Applicant, is specifically discouraged by the Galib reference as set forth above.

Accordingly, claims 10, 15 and 20 are patentable over Galib in view of Sahatjian. Claims 11-14 depend from claim 10 and, likewise, are patentable over Galib in view of Sahatjian. Claims 16-19 depend from claim 15 and, likewise, are patentable over Galib in view of Sahatjian.

Claims 1 and 8 have been rejected under 35 U.S.C. §103(a) as being unpatentable over Peyman in view of Galib and Sahatjian. The Office states:

> Peyman appears silent with regard to exactly how the IOL is inserted through the eye however, Peyman does teach that in the deflated condition it is sufficiently small to enable the IOL to be inserted into the eye through a relatively small incision. The manner and means of inserting it is not detailed. Galib teaches the process of inserting the IOL using a moveable member and Sahatjian teaches the conventional outer member as noted above. It would have been obvious to one of ordinary skill in the art to modify Peyman to insert the Peyman device using the inner and outer members as taught by Galib and Sahatjian as noted above to aid in implanting the IOL through the relatively small incision.

Applicants respectfully traverse this rejection.

Applicants claim, in claim 1, an intraocular lens system comprising an insertion and injection device and a deflated lens member having an interior. The insertion and injection device includes a moveable member having an outlet port. The movable member is housed within an outer member. The deflated lens member is mounted about and to an end of the moveable member such that the deflated lens member is sealingly engaged with a portion of the moveable member so that the interior of the deflated lens member forms a compartment. The moveable member outlet communicates with the deflated lens compartment. Further, the deflated lens member includes a self-sealing mechanism in which the insertion and injection device is removably and sealingly received such that the insertion and injection device can be removably and sealingly received in the self-sealing mechanism repeatedly.

The Peyman reference describes an intraocular lens that has an expandable or fillable bag. As acknowledged by the Office: "Peyman appears silent with regard to exactly how the IOL is inserted through the eye." Thus, as acknowledged by the Office, the Peyman reference does not describe or otherwise suggest an insertion and injection device as required by claim 1. Further, the Peyman reference does not describe or otherwise suggest an insertion and injection device that includes a moveable member housed within an outer member as required by claim 1. Still further, the Peyman reference does not describe or otherwise suggest an insertion and injection device removalby and sealingly received in a self-sealing mechanism of the deflated lens such that the insertion and injection device can be removably and sealingly received in the self-sealing mechanism repeatedly, as required by claim 1.

The Galib reference does not remedy these deficiencies of the Peyman reference. Rather, Galib merely describes placing a deflated lens onto a hollow rod or stylet for insertion into the eye. Galib does not describe or otherwise suggest an outer member surrounding the rod or styled. On the contrary, as set forth above, Galib teaches away from using such an outer member. Further, the Galib reference does not describe or otherwise suggest an insertion and injection device removalby and sealingly received in a self-sealing mechanism of the deflated lens such that the insertion and injection device can be removably and sealingly received in the self-sealing mechanism repeatedly. The Sahatjian reference, likewise, does not remedy these deficiencies of the Peyman reference. Rather, Sahatjian merely describes a bodily sample collection balloon catheter. The balloon catheter described by the Sahatjian reference does not describe or otherwise suggest an insertion and injection device removably and sealingly received in a self-sealing mechanism of a deflated lens an insertion and injection device removalby and sealingly received in a self-sealing mechanism of the deflated lens such that the insertion and injection device can be removably and sealingly received in the self-sealing mechanism repeatedly, as required by Applicants' claim 1. Rather, the balloon of the Sahatjian reference remains secured to the catheter device at all times.

CONCLUSION

Reconsideration and allowance of claims 1-20 is respectfully requested in view of the foregoing discussion. This case is believed to be in condition for immediate allowance. Applicant respectfully requests early consideration and allowance of the subject application.

Applicants believe that no extension of time is required since this response is being filed before the expiration of the specified time period. Applicants, however, conditionally petition for an extension of time to provide for the possibility that such a petition has been inadvertently overlooked and is required. As provided below charge Deposit Account No. **04-1105** for any required fee.

Should the Examiner wish to discuss any of the amendments and/or remarks made herein, the undersigned attorney would appreciate the opportunity to do so.

Respectfully submitted,

Date: 4/4/03

Lisa Swiszcz Hazzard (Reg. No. 44,368)
Dike, Bronstein, Roberts & Cushman
Intellectual Property Group of
EDWARDS & ANGELL, LLP
P.O. Box 9169
Boston, MA 02209
Tel. No. (617) 517-5512

VERSION WITH MARKINGS TO SHOW CHANGES MADE IN CLAIMS

Please note that additions to the claims are shown underlined and deletions are shown in brackets.

1. An intraocular lens system comprising [and] an insertion and injection device and a deflated lens member having an interior;

wherein the insertion and injection device includes:

a moveable member having a outlet port provided therein,

an outer member in which is disposed the moveable member,

wherein the deflated lens member is mounted about and to an end of the moveable member such that the deflated lens member is sealingly engaged with a portion of the moveable member so that the interior of the deflated lens member forms a compartment, [and]

wherein the moveable member outlet communicates with the deflated member compartment, and wherein the deflated lens member includes a self-sealing mechanism in which the insertion and injection device is removably and sealingly received such that the insertion and injection device can be removably and sealingly received in the self-sealing mechanism repeatedly. self sealing opening that is flush/continuous with the surrounding portion of the lens

2. The intraocular lens system of claim 1, wherein the moveable member and the deflated lens member mounted thereon are [moveable] movably disposed within the outer member such that the moveable member is movable between a first position and a second position, the second position corresponding to a deployed condition of the deflated lens member external to the outer member.

7. The intraocular lens system of claim 1, wherein the deflated lens member includes a self-sealing mechanism [in] which is removably and sealingly received by the moveable member.

9. An intraocular lens system comprising [and] an insertion and injection device and a deflated lens member having an interior;

wherein the insertion and injection device comprises an outlet member, the deflated lens member is mounted to the outlet member, and wherein the deflated lens member includes a self-sealing mechanism in which the insertion and injection device is removably and sealingly received such that the insertion and injection device can be removably and sealingly received in the self-sealing mechanism repeatedly.

VERSION WITH MARKINGS TO SHOW CHANGES MADE IN SPECIFICATION

Please note that additions to the specification are shown underlined and deletions are shown in brackets.

Page 2 line 7 - page 3, line 3:

As a result of these limitations, the treatment of cataracts has developed to include the implantation of an artificial lens, typically called an intraocular lens, in the eye to mimic the function of the original natural lens. With implanted intraocular lenses, there is little or no magnification or [distorition] distortion. Also, there is no need to remove the intraocular lens from the eye or otherwise handle the lens. Generally, intraocular lenses provide good visual acuity at all times, even at night.

Intraocular lenses have definite advantages in terms of vision and convenience over the other methods of aphakic correction. Intraocular lens [implanation] implantation surgery, however, is more traumatic than simple cataract extraction alone. The additional handling of the cornea and manipulation inside the anterior chamber during lens [implanation] implantation add to the amount of trauma to the eye. Extreme care must be exercise to limit trauma to the cornea, structures of the anterior chamber, and other structures. In this microfine surgery uncommon agility on the part of even a skilled surgeon often is required. Space limitations in the eye, the required size of the lens once implanted, and considerable manipulations of the lenses during implantation by the surgeon can result in traumatic damage to the corneal endothelium and very often rupture of the posterior capsule by the novice. Damage to the corneal endothelium and rupture of the posterior capsule are complications considered serious.

Initially, the intraocular lens was a relatively rigid lens requiring a 7-8 mm incision to be made in the conjunctiva and sclera just outside the cornea so that the patient's lens can be removed and replaced with an implant intraocular lens. Incision length is dictated more by the size of the intraocular lens to be implanted than by the requirement of removing the patient's natural lens. For example, since the [developement] development of the phacoemulsification technique, the patient's

natural lens can be removed using an ultrasonic instrument that requires a corneal incision of about 2-3 mm which is much smaller than is needed to insert a rigid intraocular lens.

Page 4, lines 18-32:

It thus would be desirable to provide a new and novel intraocular lens system as well as related devices and intraocular lens, so as to minimize haptic breakage and concerns with lens manipulation within the lens capsule. It would be particularly desirable to provide such systems, devices, lens and methods related thereto whereby such insertion can be achieved while using minimally sized incisions as in comparison to that for prior art techniques and lens. It also would be desirable to provide such a lens that provides a mechanism for selectively adjusting the refractive power of the lens by means of regulating the material being injected. It also would be yet more desirable to provide such a lens whereby the refractive power can be adjusted following implantation at a later time during the life of the patient to compensate for changing conditions of the eye. Such lens, insertion [devicea] devices and systems preferably would be simple in construction than prior art devices, lens and systems and such methods would not be unduly complex as compared to prior art methods.

Page 9, lines 16-27:

The second position of the plunger member 130 generally corresponds to a fully extended flexible bag position, the condition of the flexible bag 142 that is established so the bag can be inflated the desired amount by the injection of the medium 150 therein via the plunger member port(s) 134. The plunger member 130 is moved from the first to the second position by any of a number of mechanisms known to those skilled in the art which can cause the plunger member to be moved back and [for the] forth between the first and second positions including mechanisms or devices that are mechanically or fluidly coupled to the plunger member to cause such motion and which are hand-operated or motor operated. In an exemplary embodiment, a motorized screw-drive type of assembly provides the motive force for so moving the plunger member.